**FOI 23/315 - DTX301 Phase 3 study for OTC deficiency**

**MHRA RESPONSE**
**6 July 2023**

Dear

Thank you for your information request, dated 28 April 2023, where you asked for

*'Under the Freedom of Information Act (FOIA), if you would be kind to enough to supply me with:*

- *Electronic copies of the a) study protocol, b) investigator brochure (IB), and c) informed consent form (ICF) received by MHRA in relation to the DTX301 Phase 3 study for OTC deficiency (Clinicaltrials.gov: NCT05345171; EudraCT: 2020-003384-25). All appropriately redacted to remove any personal or data protection material.*

*I understand from ClinicalTrials.gov posting that the study is ongoing with a UK study site in Birmingham.'*

Unfortunately, the information is exempt from release under sections:

Section 41 – Information provided in confidence: information provided to us in confidence, with the expectation that it will not be released, is exempt from disclosure under the FOI Act. Information will be covered by Section 41 if: it was obtained by the authority from any other person; its disclosure would constitute a breach of confidence; a person or organisation could bring a court action for that breach of confidence; and that court action would be likely to succeed. Section 41 is an absolute exemption and no consideration of the balance of public interest is required.

Section 43 – Commercial interests: information where disclosure would be likely to prejudice the commercial interests of any person, including third parties or the public authority that holds the information. Section 43 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. We have considered the public interest and cannot see any overriding argument for releasing the information that outweighs the commercial harm by providing potential competitors with an insight into the product development and design of these studies. As a market regulator, it is vital that the Agency can freely engage in dialogue with organisations about commercial activities.

Furthermore, I can confirm that the MHRA does not hold the information to informed consent documentation that you have requested.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

**MHRA Customer Experience Centre**
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